

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



54

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁵ : A61K 31/765	A1	(11) International Publication Number: WO 93/25211 (43) International Publication Date: 23 December 1993 (23.12.93)
(21) International Application Number: PCT/US93/05812 (22) International Filing Date: 16 June 1993 (16.06.93) (30) Priority data: 07/897,988 16 June 1992 (16.06.92) US (60) Parent Application or Grant (63) Related by Continuation US 07/897,988 (CON) Filed on 16 June 1992 (16.06.92) (71) Applicant (for all designated States except US): EMBRO RE- SEARCH CORPORATION [US/US]; 6320 Southwest 13th Street, Gainesville, FL 32608 (US).		(72) Inventor; and (75) Inventor/Applicant (for US only) : EMBRO, William, J. [US/US]; 7402 Northwest 18th Avenue, Gainesville, FL 32608 (US). (74) Agents: SUTER, Stuart, R. et al.; SmithKline Beecham Corporation, Corporate Patents - U.S., UW2220, 709 Swedeland Road, P.O. Box 1539, King of Prussia, PA 19406-0939 (US). (81) Designated States: AU, BB, BG, BR, BY, CA, CZ, FI, HU, JP, KP, KR, KZ, LK, MG, MN, MW, NO, NZ, PL, RO, RU, SD, SK, UA, US, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>
(54) Title: TREATMENT FOR CUTANEOUS PAIN, ITCHING AND INFLAMMATION WITH TOPICAL STANNOUS FLUORIDE (57) Abstract The present invention provides a treatment for the cutaneous pain, itching and inflammation associated with allergies, burns, trauma, insect bites and bacterial, viral and fungal infections. According to the invention, a non-toxic amount of stannous fluoride is incorporated into a suitable pharmaceutical carrier and administered topically.		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	MR	Mauritania
AU	Australia	GA	Gabon	MW	Malawi
BB	Barbados	GB	United Kingdom	NL	Netherlands
BE	Belgium	GN	Guinea	NO	Norway
BF	Burkina Faso	GR	Greece	NZ	New Zealand
BG	Bulgaria	HU	Hungary	PL	Poland
BJ	Benin	IE	Ireland	PT	Portugal
BR	Brazil	IT	Italy	RO	Romania
CA	Canada	JP	Japan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SK	Slovak Republic
CI	Côte d'Ivoire	LJ	Liechtenstein	SN	Senegal
CM	Cameroon	LK	Sri Lanka	SU	Soviet Union
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	MC	Monaco	TG	Togo
DE	Germany	MG	Madagascar	UA	Ukraine
DK	Denmark	ML	Mali	US	United States of America
ES	Spain	MN	Mongolia	VN	Viet Nam
FI	Finland				

TREATMENT FOR CUTANEOUS PAIN, ITCHING AND INFLAMMATION
WITH TOPICAL STANNOUS FLUORIDE

5

BACKGROUND OF THE INVENTION

10 The present invention relates to a treatment for the cutaneous pain, itching and inflammation often associated with allergies, burns, trauma, insect bites and bacterial, viral and fungal infections. More particularly, the invention relates to the topical application of stannous fluoride for the treatment of such symptoms.

15 A large number of pharmaceutical preparations, as well as other forms of treatment, have been developed for administration to patients suffering from the pain, itching or inflammation which accompanies allergies, burns, infections and the like. Antihistamines, analgesics, corticosteroids and astringent dressings are typical of such treatments. However, it is often the case that such treatments are either ineffective or marginally effective, have associated undesirable side effects or are prohibitively expensive, especially when long term administration is required.

20 It is, therefore, an object of the present invention to provide a treatment for cutaneous pain, itching and inflammation which is effective, safe and inexpensive.

SUMMARY OF THE INVENTION

25 The present invention meets this object by providing a treatment which includes the topical application of stannous fluoride. A non-toxic amount of stannous fluoride is incorporated into a pharmaceutical carrier, such as a gel, ointment, cream, lotion or the like, and applied at the site of the inflammation, itching or lesion. Preferably, the stannous fluoride is provided in a concentration
30 ranging from about 0.1 wt. % to about 8 wt. %. Most preferably, the stannous fluoride is applied as a 0.4% SnF₂ glycerin-based gel. The frequency of application may range anywhere from one to six times a day or on an as needed basis. The course of therapy typically ranges from one to ten days but may be continued as long as required for complete relief.

35

DETAILED DESCRIPTION OF THE INVENTION

A non-aqueous stannous fluoride gel is prepared by solubilizing SnF_2 in glycerin at approximately 150°F for four hours. The resulting gel is a stable
5 solution having an indefinite shelf life that is ideal for topical application to the skin and mucosal tissues. As the following examples demonstrate, stannous fluoride promotes relief from pain, itching and inflammation; however, the mechanism by which the compound effects these results is not clearly understood. It is
10 hypothesized that both tin (Sn^{++}) and fluoride (F^-) ions interact together and affect nerve action potentials, histamine release, cellular enzyme systems and vascular systems, all of which can influence the pain, itching and inflammation caused by infection, allergies and trauma.

EXAMPLE 1

Two patients exhibiting an allergic reaction to poison ivy were instructed to
15 apply 0.4% SnF_2 gel 4 to 6 times a day or on an as needed basis. Relief from pain and itching was obtained almost immediately.

EXAMPLE 2

Five patients with burns were instructed to apply 0.4% SnF_2 gel 4 to 6
20 times a day or on an as needed basis. Relief from the pain associated with the burns was obtained almost immediately.

EXAMPLE 3

Ten patients having insect bites (7 mosquitoes, 2 bees) received immediate relief from the associated pain, inflammation and itching when 0.4% SnF_2 gel was applied.

25

EXAMPLE 4

Three patients received pain relief from cuts on the skin when 0.4% SnF_2 gel was applied to the lesions.

EXAMPLE 5

Fifteen patients infected with herpes zoster virus and 30 patients infected
30 with herpes simplex virus were instructed to apply 0.4% SnF_2 gel 4 to 6 times a day. The pain and itching associated with the infections was either eliminated completely or significantly reduced.

EXAMPLE 6

Eight patients having acne infections of bacterial origin on the skin obtained
35 relief from the pain associated with the infections when 0.4% SnF_2 gel was applied.

EXAMPLE 7

Two patients infected with ringworm and eight patients infected with athletes foot were instructed to apply 0.4% SnF₂ gel 4 to 6 times a day or on an as needed basis. Relief from the itching and pain associated with the infections was
5 obtained almost immediately.

While preferred embodiments have been shown and described, various modifications and substitutions may be made without departing from the spirit and scope of the invention. Accordingly, it is to be understood that the present invention has been described by way of example and not by limitation.

What is claimed is:

1. A method of treating cutaneous pain, itching and inflammation comprising: topically applying a non-toxic amount of stannous fluoride
5 incorporated into a pharmaceutical carrier.
2. The method of claim 1 further characterized in that the stannous fluoride is provided in a concentration ranging from about 0.1 weight percent to about 8
10 weight percent.
3. The method of claim 1 wherein the pharmaceutical carrier is a gel, ointment, cream or lotion.
4. The method of claim 1 further characterized in that the stannous fluoride
15 is applied as a 0.4 weight percent glycerin-based gel.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US93/05812

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61K 31/765

US CL :424/486

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/486, 650

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,563,489 (URIST) 07 JANUARY 1986 See entire document.	1-4
Y	US, A, 4,639,366 (HELLER) 27 JANUARY 1987 See entire document.	1-4
Y	US, A, 5,013,649 (WANG) 07 MAY 1991 See entire document.	1-4
Y	US, A, 5,024,841 (CHU) 18 JUNE 1991 See entire document.	1-4

☐

Further documents are listed in the continuation of Box C.

☐

See patent family annex.

* Special categories of cited documents:	* T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
* A* document defining the general state of the art which is not considered to be part of particular relevance	* X*	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
* E* earlier document published on or after the international filing date	* Y*	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
* L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	* Z*	document member of the same patent family
* O* document referring to an oral disclosure, use, exhibition or other means		
* P* document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

11 AUGUST 1993

Date of mailing of the international search report

20 SEP 1993

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. NOT APPLICABLE

Authorized officer

WILLIAM E. BENSTON, JR.

Telephone No. (703) 308-2351